MAR 2 1 2006

K060206

510(k) Summary

for Mission Diagnostic pH/Blood Gas ISE, Metabolite Controls for pH/Blood Gas, Electrolyte and Metabolites Analyzers

1. **Submitter's Name & Address**

Diamond Diagnostics
333 Fiske St
Holliston MA 01746
FAX: 508-429-0452

Contact Person:
Randolph Quinn
Product Development & Compliance Manager
508-429-0450

Establishment Registration Number: 3003656721
Date of Preparation of this summary: January 18, 2006

2. **Identification of the Device:**

Proprietary/Trade name:	Mission Complete™
Common or usual name	Quality Control material (assay and unassayed)
Classification name:	Multi-Analyte Controls (assay and unassayed)
Device Classification	I
Regulation Number:	21 CFR § 862.1660
Panel:	Chemistry (75)
Product Code:	JJY

3. **Substantial Equivalence:**
Mission Complete PN DD-92900 is equivalent to RNA Medical CVC 123 with regards to function, safety and efficacy.

Comparison Tables of Characteristics

Characteristics	Mission	OEM Equivalent
PN	DD-92900	CVC 123
Contents: Any Level	Aqueous solution of buffers, electrolytes, glucose, lactate,equilibrated with , CO_2, O_2, and N_2. Contains no human or animal materials.	Aqueous solution of buffers, electrolytes, glucose, lactate,equilibrated with , CO_2, O_2, and N_2. Contains no human or animal materials.
Levels	1,2,3,4,5	1,2,3,4,5
Container	Glass ampule	Glass ampule
colour	clear	clear
Package	20 x 1.8 ml	20 x 2.5 ml
Intended Use	For in-vitro diagnostic use only	For in-vitro diagnostic use only
Storage	2° - 8°C	2° - 8°C
Expiration/Shelf Life	3 years	3 years

4. **Description of the new device:**
This control material is provided in five (5) distinct levels of pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glucose & Lactate covering the significant range of the instrument performance. It is packaged in sealed glass ampules, each containing 1.8 ml of solution. Ampules are packaged in kits containing four (4) ampules of each level.

5. **Intended use of the device:**
MISSION COMPLETE™ Linearity Control are assayed materials used for confirming the calibration and linearity of blood gas, electrolyte, and metabolite instruments for the analytes and analyzers listed on the Expected Values Chart.

6. **Technological characteristics of the device:**
This material consists of a buffered aqueous solution with electrolytes, glucose and lactate equilibrated with CO2, O2 and N2. The product contains no human or animal derived materials. Product is sealed into glass ampules containing 1.8mL and is intended for onetime use.

7. **Summary of non-clinical tests submitted with the premarket notification for the device:**
   a) Stability for shelf life claim
   b) Performance & Correlation to equivalent device

8. **Summary of clinical tests submitted with the premarket notification for the device:**
N/A

9. **Conclusions drawn from the clinical and non-clinical trials:**
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 1 2006

Mr. Randolph Quinn
Development & Compliance Manager
Diamond Diagnostics, Inc.
333 Fiske Street
Holliston, MA 01746

Re: k060206
Trade/Device Name: Mission Complete™ Linearity Controls
Regulation Number: 21 CFR§ 862.1660
Regulation Name: Quality Control (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: January 26, 2006
Received: February 15, 2006

Dear Mr. Quinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060206

Device Name: Mission Complete

Indications For Use:

Mission Complete™ Linearity Controls are intended to be used for confirming the calibration and linearity of instruments measuring pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, and Lactate.

For *In Vitro* Diagnostic Use

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safe

510(k) K060206